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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/950,963	10/15/1997	JOEL A. DREWES	074022-3302	9997

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/950,963

Applicant(s)

DREWES ET AL.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 18-34, & 36-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18-34, and 36-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 3/16/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 1-12, 18-34, and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Channels that are "continuous" have been added as a claim limitation in claims 1, 2, 5, 6, 18, 19, and 23. Review of instant claims 3 and 4 as originally filed revealed that they did not contain such a "continuous" limitation which is present in these claims in their present form. Applicants pointed to written support for this amendment in pages 15 and 5-9 of the specification. Consideration of these citations revealed that the now amended channels that are "continuous" through each of the claimed layers is not found in these citations nor elsewhere in the disclosure as filed. These citations indicate that laminar flow is present as well as layers therein but not that the flow is specifically "continuous" through these layers. Laminar flow may occur in sections of a fluid device without this necessarily causing such flow to be continuous between various elements

Art Unit: 1631

of a device. It is acknowledged that the word "continuous" is cited on page 7, line 7, of the instant specification but that this disclosure is directed to sample being pulled or pushed either continuously or in a discrete volume which lacks written support for the continuous disposition of channels through layers. Claims which are directly or indirectly dependent from claims 1-6, 18, 19, or 23 also contain this NEW MATTER due to their dependence.

VAGUENESS AND INDEFINITENESS

Claims 1-12, 18-34, and 36-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 1-11, describes elements of the claimed optical assay device without any mention of on what or where a "surface" is present therein. Also, several layers are cited in lines 4-11 wherein certain of the layers are cited as being positioned on other specified layers but without a clear definition of the cooperativity or positioning of said layering relative to the support cited in line 3. In the last 3 lines of claim 1 laminar flow is provided including a limitation regarding flow "from the surface of said device" without providing antecedent basis as to where this surface is in the device. This lack of antecedent basis as to surface disposition in the claimed device as well as the lack of defining the metes and bounds of the positioning of the layers relative to the support in line 3 of claim 1 causes the claim to be vague and indefinite as to what is meant thereby. One attempt at interpreting the claims is that the surface may be positioned broadly anywhere relative to the layers and support. This, however, causes

Art Unit: 1631

uncertainty as the surface in the last three lines of claim 1 is part of a continuous flow limitation that seems to be related to the continuous flow in item (i) of claim 1 which may limit the location of the surface relative to each of the layers cited in said item (i). Thus, the broadly defined surface interpretation conflicts with some undefined relationship(s) between wherever the surface is compared to each of the defined layers. Claims 2-6, 18, 19, and 23 also contain the above uncertainties. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claims 1-6, 18, 19, or 23 also contain this uncertainty due to their dependence.

Claims 39 and 40 also cite a support with two or three, respectively, layers which are not clearly and concisely defined as to the relationship between the positions of the two layers and the support. That is, which layer is directly on the support vs. a layer upon a layer? Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claims 39 or 40 also contain this uncertainty due to their dependence.

In claim 1, line 3, channels are cited in a support. In claim 1, line 10, channels are also cited, therein provided via configuration and arrangement of the support and three layers. It is not clear that these channels are the same nor is there a limitation to that effect. In claim 1, line 12, the phrase "said channels" lacks clear antecedent basis as to whether the line 3 channels are meant or the line 12 channels. Clarification via clearer claim wording is requested. This uncertainty is also present in claims 2-6, 18, 19, and 23 regarding citing "said channels" where multiple apparently different channels

Art Unit: 1631

precede the citation in the claims. Claims dependent from claims 1-6, 18, 19, or 23 also contain this unclarity due to their dependence.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-12, 23, 24, 26-34, and 36-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51, 52, 54, 55, 57-63, 66-68, 70, 71, 73-79, and 82 of copending Application No. 09/675,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record which have not been argued by applicants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

May 28, 2004

Ardin H. Marschel 5/28/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER